

Appl. No. 09/585,820
Amdt. Dated April 27, 2004
Reply to Office Action of December 12, 2003

REMARKS/ARGUMENTS

Claims 16, 20, 22, 23, and 25-51 were pending in the parent application.

After entry of this Amendment, claims 1-15, 17-19, 21, 24-28, 30, 38, 44, 47-48, and 50 are canceled and claims 16, 20, 22, 23, 29, and 31-37, 39-43, 45-46, 49 and 51 remain in this case. Claims 29, 31, 33, 36, 39, 42, 45 and 46 have been amended. It is respectfully submitted that the amended claims are fully supported in the specification as filed and that no new matter has been added.

Rejection under 35 U.S.C. §112 second paragraph

In the Final Rejection, claims 16, 20, 22, 23, 25-41, 44, 47 and 49-51 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In particular, the Examiner avers that claims 16, 20, 29, 22, 23 and 49 positively claim identical subject matter as claimed in claims 25, 26, 30, 27, 28 and 50, respectively, and differ only in the intended use recitations of their preambles, which the Examiner avers do not serve to distinguish the same subject matter from itself. Without acquiescing in the rejection of claims and solely to advance prosecution of the application, Applicants have canceled claims 25, 26, 30, 27, 28 and 50, thus rendering the rejection moot.

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The Examiner further avers that in claims 29, 30, 33 and 39, and claims 22, 23, 27, 28, 34, 35, 40, and 41 dependent thereupon, "the single test" lacks antecedent basis. Claims 30, 27 and 28 have been canceled thus rendering this rejection moot as to those claims. Claims 29, 33, and 39 have been amended. It is respectfully submitted that these amendments fully address the rejection and that the rejection should be withdrawn.

The Examiner further avers that in claims 29, 30, 33, 39, 44 and 47, the interrelationships of the components are not clear because it is not clear how the recited alternatives relate to the previously recited "single column". Applicants have canceled claims 30, 44 and 47, thus making this rejection moot as to that claim. Claims 29, 33, and 39 were amended in a manner to more clearly set forth the interrelationships of the components; reference to "single test" has been deleted and these claims now relate to single column embodiments. It is respectfully submitted that such amendments overcome the rejection and that the rejection should be withdrawn.

The Examiner further avers that in claims 31-35 and 51, it is not clear what is being determined because the interrelationships of antigens borne on the cell populations to reverse ABO type determined in step d) are not clear. Claim 31 has been amended to recite that the claim is directed to ABO antibody testing and step d) is amended to make clear that what is determined is ABO type. It is respectfully submitted that this amendment

addresses the Examiner's rejection and that this rejection might respectfully be withdrawn.

The Examiner further avers that in claims 36-41 the interrelationships of the steps and components are not clear, for example because: the relationship of antibody to sample or admixture is not clear; the relationship of antibody to first or second antigen or to agglutinate is not clear. Applicants have canceled claim 38 as redundant to claim 36 step (a).

Applicants respectfully submit that claim 36 is fully supported in the specification as filed at for example page 10 line 32 to page 11 line 16. With particular reference to the use of 2 reagent red blood cell populations bearing antigens wherein one population is stained, see the specification as filed at page 22, lines 6-14, discussing the ability to alter the color of one reagent red cell population which, after admixture with test sample containing antibody to one of the reagent red cell antigens, forms an identifiably colored agglutinate. Further, at page 31 lines 5-19 of the specification, there is a working example that supports claim 36, wherein it is described how in one column there is combined: (1) reagent red cells of 2 antigen types (A1 and B), wherein the B reagent red cells were colored brown; with (2) group B sera, which is the sample of blood as stated in the claim. This disclosure supports claim 36 (a) wherein it is stated "admixing a sample of blood with reagent red blood cells bearing a first antigen and reagent red blood cells bearing a second

antigen, wherein one of the populations of red blood cells is stained".

Applicants respectfully submit that the above fully addresses the rejection and that the rejection might respectfully be withdrawn. Alternatively, if the Examiner perceives a continuing issue in this respect, Applicants respectfully request that the Examiner contact Applicants' undersigned attorney and more particularly set forth the rejection and perhaps make a specific request concerning how the rejection might be overcome.

The Examiner avers that Applicants urged that claims 16 and 25 do not claim identical subject matter because the preamble of claim 25 indicates narrower subject matter than that of claim 16; that such is not found persuasive because the preambles have not been accorded any patentable weight which distinguished the claimed subject matter because the preambles merely recite the purpose of identically claimed processes for reverse ABO typing, not for alternative processes for determination of different scopes of antibodies to erythrocyte antigens as would appear Applicants' allegation. Without acquiescing in the rejection and solely to advance prosecution, Applicants have canceled claim 25 herein. Applicants thus respectfully submit that the rejection has been overcome and should be withdrawn.

The Examiner further avers that with regard to claims 36-41, Applicants asserts that pages 24-25 of the specification set forth the method of screening for determination of antibodies; that such is not found

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persuasive because claims must particularly point out and distinctly claim the subject matter which Applicants regard as the invention and, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Claim 38 has been canceled thus rendering this rejection moot as to claim 38. Applicants believe claim 36 incorporates the necessary limitations of the specification as to that embodiment. Applicants refer the Examiner to the preceding paragraph wherein Applicants describe how the specification at page 31 lines 5-19 in particular support claim 36. If the Examiner perceives a continuing issue in this respect, Applicants respectfully request that the Examiner contact the undersigned attorney and more particularly set forth the rejection and perhaps make a specific request concerning how the rejection might be overcome.

Rejection Under 35 USC 102(b)

Claims 42-44 and 46-47 were rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Ullman (U.S. Pat. No. 4,584,277) for reasons of record. The Examiner avers that Applicants' arguments of December 23, 2002 have been fully considered but they are not deemed persuasive; that Applicants urge that newly presented recitations of intended use for a column or for the reagents in particular method steps serve to distinguish the subject matter of the instant claims from the reagents disclosed in the reference; that this is not found persuasive because recitations of intended use are accorded patentable weight only to the extent that they

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limit the actual components of the kit; that in the instantly rejected claims the intended use does not affect the components in any way which distinguishes over the subject matter taught or suggested by the reference.

Claims 44, 47 and 48 has been canceled. Applicants have amended claims 42 and 46 to recite in the body of the claims thereof that the reaction means which are component (b) of the claimed kit recite performing the antibody test "wherein said reaction means consists of a tube or column agglutination reaction vessel". Having thus amended the body of the claim it is respectfully submitted that the rejection has been overcome and should be withdrawn.

Rejection Under 35 USC 102(b) and 103(a)

Claims 36-40 were rejected under 35 U.S.C. 102(b) as being anticipated by Yves [Lapierre] et al. (U.S. Pat. No. 5,338,689) for reasons of record.

Claims 36-40 were rejected under 35 U.S.C. 102(b) as being anticipated by Chachowski et al. (U.S. Pat. No. 5,552,064) for reasons of record.

Claims 36-48 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chachowski et al. (U.S. Pat. No. 5,552,064) in view of Shen et al. (U.S. Pat. No. 5,594,808) for reasons of record.

The Examiner avers that Applicants' arguments filed December 23, 2002 have been fully considered but are not

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deemed to be persuasive; that Applicant urges that the claims as amended overcome the teachings of the references of Yves [LaPierre] et al (U.S. Patent No. 5,338,689), alone, or Chachowski et al (U.S. Patent No. 5,552,064), alone or as modified, because these references fail to show performance in a single column; that this is not found persuasive for the instantly rejected claims because the recitation "in a single column" has not been given patentable weight because the recitation occurs in the preamble; that a preamble is not generally accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness, but, instead, the process steps or structural limitations are able to stand alone, making reference to *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claims 38, 44 and 47-48 have been canceled thus rendering this rejection moot as to those claims.

Claims 36, 42 and 46 have been amended to recite that the method (or the method of the kit) is performed "in a single column" in the claim body of these claims, as requested by the Examiner. For these reasons, it is believed and respectfully submitted that the rejection has been overcome and the rejection should be withdrawn.

For the above-stated reasons and in light of Applicants' amendments made herein, it is respectfully submitted that the claims are patentable over the

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rejections and art cited. Applicants therefore respectfully request that the rejections be withdrawn and the claims be allowed.

Please charge the fees due in connection with the filing of this Amendment to Deposit Account No. 10-0750/CDS-221/CKG in the name of Johnson & Johnson.

Respectfully submitted,


Catherine Kurtz Gowen
Attorney for Applicants
Registration No. 32,148

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Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Telephone No. 732-524-2681
Facsimile No. 732-524-2134